

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 42-129 are pending in the application, with claims 42, 48, 58, 64, 69, 75, 85, and 91 being the independent claims. New claims 103-129 are sought to be added.

It is believed that the amendments presented above will place the application in condition for allowance and/or in better form for appeal. *See* 37 CFR § 1.116(a). Specifically, the independent claims have been amended to incorporate, in part, subject matter that was found in the dependent claims. The dependent claims have been amended accordingly to provide correspondence with the language added to the independent claims. New claims 103-129 specify the growth rate of the *E. coli* of the respective base claims. Thus, the amended and new claims introduce no new matter and present no new issues requiring further consideration or search. It is therefore respectfully requested that the amendments after final action be entered. *See id.*

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Support for Amended and New Claims

Support for the amendments to claims 42-50, 55-75, 79-85 and 88-102 can be found, *inter alia*, in the specification at page 10, line 14-33.

Support for new claims 103-129 can be found, *inter alia*, in the specification at page 10, lines 18-23.

II. Claim Rejections Under 35 USC § 112, Second Paragraph

Claims 42-102 have been rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. *See* Paper No. 10, page 2. The basis for this rejection is the Examiner's assertion that the expression "rapid growing" is a relative term which renders claims 42-102 indefinite. *See* Paper No. 10, page 2. The Examiner noted that the specification defines a rapid growing microorganism as having a growth rate of 5% - 200% increased as compared to a reference microorganism. *See* specification at pages 2-3. The Examiner contended, however, that "[t]here is no definitive reference microorganism, nor is there defined culture conditions for ascertaining increased growth of a microorganism. Thus, any microorganism can be considered rapid growing." *See* Paper No. 10, page 3. Applicants respectfully traverse this rejection.

Applicants maintain that the term "rapid growing" is clearly defined in the specification as a microorganism that grows more rapidly than *E. coli* K-12 derived strains typically used in molecular biology applications. *See* specification at page 10, lines 14-16. Rapid growing microorganisms, including rapid growing *E. coli*, are identified on the basis of their growth rate as compared to a reference microorganism. *See* specification at page 10, lines 16-22. Relative growth rate can be ascertained, *e.g.*, on the basis of colony size or doubling time. *See* specification at page 15, lines 3-11. Reference microorganisms include *E. coli* MM294 (ATCC33625) as well as DH5 α , DH10B, and "any other strain routinely

used in cloning applications." *See* specification at page 10, lines 22-25. Finally, the culture conditions necessary for ascertaining whether a given microorganism has an increased growth rate, relative to a reference microorganism, were known by, or readily available to, those skilled in the art at the time the application was filed. *See* specification at page 15, lines 6-11.

Nevertheless, solely to expedite prosecution, Applicants have deleted the expression "rapid growing" as a modifier of the term "*E. coli*" in the claims. In addition, Applicants have inserted into the claims where appropriate the phrase "having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B." Thus, the Examiner's basis for the rejection under 35 USC § 112, second paragraph, does not apply to any of the claims as currently presented. Accordingly, Applicants respectfully request that the rejection of claims 42-102 under 35 USC § 112, second paragraph, be withdrawn.

III. Claim Rejections Under 35 USC § 102

The Examiner has made four separate rejections under 35 USC § 102, each of which is addressed in turn below. The basis for each of these § 102 rejections is the Examiner's contention that "the term 'rapid growing' is . . . indefinite." *See, e.g.*, Paper No. 10, page 4. Applicants respectfully traverse this contention. Nevertheless, since Applicants have removed the expression "rapid growing" from the present claims, the Examiner's basis for the rejections under § 102 has been obviated and should be withdrawn.

Furthermore, Applicants submit that none of the references cited by the Examiner anticipate the claims as currently presented. Under 35 USC § 102, a claim can only be

anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.") As discussed in more detail below, none of the references cited by the Examiner contain all of the elements of any of Applicants' presently presented claims. Thus, Applicants respectfully submit that the rejections under 35 USC § 102 do not apply to the amended claims.

A. *Bharathi et al.*

The Examiner has rejected claims 42 and 64 under 35 USC § 102(b) as being anticipated by Bharathi *et al.*, *FEMS Microbiol. Lett.* 84:37-40 (1991) ("Bharathi"). *See* Paper No. 10, page 4. According to the Examiner, Bharathi discloses a strain of *E. coli* that lacks endogenous plasmids and a method for making the strain. *See* Paper No. 10, page 4. Applicants respectfully traverse the rejection.

Claim 42, as currently presented, is directed to isolated *E. coli* lacking endogenous plasmids and having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B. Claim 64, as currently presented, is directed to a method of producing *E. coli* for cloning, comprising: (a) obtaining *E. coli* having endogenous plasmids and having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected

from the group consisting of *E. coli* MM294, DH5 α and DH10B; and (b) curing said *E. coli* of endogenous plasmids.

Bharathi does not teach *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B. Nor does Bharathi teach methods of producing such *E. coli*. In fact, the Bharathi reference does not even specify the full genotype of the *E. coli* strains used in the experiments described therein; furthermore, there is no guidance provided in Bharathi directing the skilled artisan to a source where one could ascertain the genotype of the strains¹. Therefore, the Bharathi disclosure is not enabling. Even assuming these *E. coli* strains were available to the public, there is no evidence that would indicate that the strains have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, DH5 α or DH10B. Thus, Bharathi cannot and does not anticipate Applicants' claims. Applicants respectfully request that the rejection of claims 42 and 64 under 35 USC § 102(b) as being anticipated by Bharathi be reconsidered and withdrawn.

B. U.S. Patent No. 4,966,841 to Riley

The Examiner has rejected claims 48 and 69 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,966,841 to Riley ("Riley"). See Paper No. 10, page 5. According to the Examiner, "Riley discloses a method of cloning enhancer fragments comprising the steps of constructing a population of recombinant cloning vectors,

¹The paragraph bridging pages 37 and 38 in Bharathi merely indicates that the *E. coli* cultures used in the experiments were obtained from the Institute of Microbial Technology in Chandigarh, India. There is no discussion of the growth rates of the strains relative to a reference microorganism.

transforming an *Escherichia coli* host strain with the recombinant cloning vectors and selecting the transformed *Escherichia coli* cells containing the recombinant vector." See Paper No. 10, page 5. Applicants respectfully traverse the rejection.

Claim 48, as currently presented, is directed to a method of cloning, comprising: (a) obtaining competent *E. coli*; (b) transforming said competent *E. coli* with at least one vector; (c) selecting transformed *E. coli* containing said at least one vector; and (d) culturing said transformed *E. coli*; wherein said *E. coli* are *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B. Claim 69, as currently presented, is directed to method of transforming a rapid growing *E. coli*, comprising: (a) obtaining competent *E. coli*; (b) incubating said *E. coli* in the presence of one or more vectors under conditions which cause said one or more vectors to be taken up by said *E. coli*; and (c) culturing said *E. coli*; wherein said *E. coli* are *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

The methods set forth in Riley do not include culturing *E. coli*, wherein the *E. coli* have a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B. Moreover, there is no evidence presented that would indicate that the *E. coli* strains used in Examples 1 and 2 of Riley (*i.e.*, RRI and JM107, respectively; see Riley at column 17, lines 5 and 28) have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, DH5 α or DH10B. Thus, Riley cannot and does not anticipate Applicants' claims.

Applicants respectfully request that the rejection of claims 48 and 69 under 35 USC § 102(b) as being anticipated by Riley be reconsidered and withdrawn.

C. *Bhandari et al.*

The Examiner has rejected claim 58 under 35 USC § 102(b) as being anticipated by Bhandari *et al.*, *J. Bacteriol.* 179:4403-4406 (1997) ("Bhandari"). See Paper No. 10, pages 5-6. According to the Examiner, Bhandari discloses a method of producing three different proteins by transforming *E. coli* cells with recombinant vectors carrying the respective genes for the proteins. See Paper No. 10, pages 5-6. The Examiner further asserted that "*E. coli* is considered to be a microorganism capable of rapid growth. Thus, claim 58 reads on the methods and host strains of Bhandari *et al.*" See Paper No. 10, page 6. Applicants respectfully traverse the rejection.

Claim 58, as presently presented, is directed to a method of producing a protein or peptide, comprising: (a) obtaining competent *E. coli*; (b) transforming into said competent *E. coli* a vector containing a gene encoding a protein or peptide; and (c) culturing said transformed *E. coli* under conditions that cause said transformed *E. coli* to produce said protein or peptide; wherein said *E. coli* are *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

Bhandari does not disclose culturing a transformed *E. coli* under conditions that cause the transformed *E. coli* to produce a protein or peptide, wherein the *E. coli* are *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

Moreover, there is no evidence presented that would indicate that the *E. coli* strains disclosed in Bhandari (*i.e.*, BL21(DE3) derivatives; *see* Bhandari at page 4404, right column, lines 12-20) have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, DH5 α or DH10B. Thus, Bhandari cannot and does not anticipate Applicants' claims. Applicants respectfully request that the rejection of claim 58 under 35 USC § 102(b) as being anticipated by Bhandari be reconsidered and withdrawn.

D. U.S. Patent No. 4,981,797 to Jessee *et al.*

The Examiner has rejected claims 85-87 and 91 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,981,797 to Jessee *et al.* ("Jessee"). *See* Paper No. 10, page 6. According to the Examiner, Jessee discloses a composition comprising rapid growing microorganisms as well as a method of making competent *E. coli*. *See* Paper No. 10, page 6. Applicants respectfully traverse the rejection.

Claims 85-87, as currently presented, are directed to compositions comprising *E. coli*, wherein said *E. coli* within said compositions have a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B. Claim 91, as currently presented, is directed to a method of making competent *E. coli*, comprising: (a) obtaining *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B; and (b) treating said *E. coli* to make it competent.

Neither the compositions nor the methods disclosed in Jessee contain or involve *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference

microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B. Moreover, there is no evidence presented that would indicate that the *E. coli* strains used in the methods of Jessee (RR1, HB101, DH1, and DH5; *see* Jessee at column 5, lines 10-18) have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, DH5 α or DH10B. Thus, Jessee cannot and does not anticipate Applicants' claims. Applicants respectfully request that the rejection of claims 85-87 and 91 under 35 USC § 102(b) as being anticipated by Jessee be reconsidered and withdrawn.

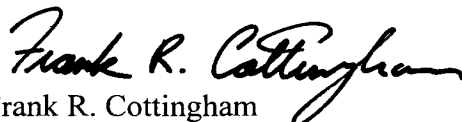
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: 5/01/02

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

42. (Once Amended) Isolated [rapid growing] *E. coli* lacking endogenous plasmids and having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

43. (Once Amended) The isolated [rapid growing] *E. coli* of claim 42, wherein said isolated *E. coli* are *E. coli* strain W or strain C.

44. (Once Amended) The isolated [rapid growing] *E. coli* of claim 43, wherein said isolated *E. coli* are selected from a group consisting of BRL3781, BRL3784 and *recA*⁻ derivatives thereof.

45. (Once Amended) The isolated [rapid growing] *E. coli* of claim 42, wherein said isolated *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

46. (Once Amended) The isolated [rapid growing] *E. coli* of claim 42, wherein said isolated *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

47. (Once Amended) The isolated [rapid growing] *E. coli* of claim 42, wherein said isolated *E. coli* have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

48. (Once Amended) A method of cloning, comprising [the steps of]:

- (a) obtaining competent *E. coli*;
- (b) transforming said competent *E. coli* with at least one vector;
- (c) selecting transformed *E. coli* containing said at least one vector; and

(d) culturing said transformed *E. coli*; [,]

wherein said [cultured] *E. coli* are [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

49. (Once Amended) The method of claim 48, wherein said [rapid growing] *E. coli* are *E. coli* strain W or strain C.

50. (Once Amended) The method of claim 49, wherein said [rapid growing] *E. coli* do not contain endogenous vectors.

55. (Once Amended) The method of claim 48, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

56. (Once Amended) The method of claim 48, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

57. (Once Amended) The method of claim 48, wherein said [rapid growing] *E. coli* have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

58. (Once Amended) A method of producing a protein or peptide, comprising [the steps of]:

- (a) obtaining competent *E. coli*;
- (b) transforming into said competent *E. coli* a vector containing a gene encoding a protein or peptide; and
- (c) culturing said transformed *E. coli* under conditions that cause said transformed *E. coli* to produce said protein or peptide; [,]

wherein said [cultured] *E. coli* are [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

59. (Once Amended) The method of claim 58, wherein said [rapid growing] *E. coli* are *E. coli* strain W or strain C.

60. (Once Amended) The method of claim 59, wherein said [rapid growing] *E. coli* do not contain endogenous plasmids.

61. (Once Amended) The method of claim 58, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

62. (Once Amended) The method of claim 58, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

63. (Once Amended) The method of claim 58, wherein said [rapid growing] *E. coli* have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

64. (Once Amended) A method of producing *E. coli* for cloning, comprising [the steps of]:

(a) obtaining [rapid growing] *E. coli* having endogenous plasmids and having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B; and

(b) curing said [rapid growing] *E. coli* of endogenous plasmids.

65. The method of claim 64, wherein said *E. coli* are *E. coli* strain W or strain C.

66. (Once Amended) The method according to claim 64, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

67. (Once Amended) The method according to claim 64, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

68. (Once Amended) The method of claim 64, wherein said [rapid growing] *E. coli* have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

69. (Once Amended) A method of transforming [a rapid growing] *E. coli*, comprising [the steps of]:

- (a) obtaining competent *E. coli*;
- (b) incubating said *E. coli* in the presence of one or more vectors under conditions which cause said one or more vectors to be taken up by said *E. coli*; and
- (c) culturing said *E. coli*; [,]

wherein said [cultured] *E. coli* are [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

70. (Once Amended) The method of claim 69, wherein said [rapid growing] *E. coli* are *E. coli* strain W or strain C.

71. (Once Amended) The method of claim 70, wherein said [rapid growing] *E. coli* do not contain endogenous plasmids.

72. (Once Amended) The method according to claim 69, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

73. (Once Amended) The method according to claim 69, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

74. (Once Amended) The method of claim 69, wherein said [rapid growing] *E. coli* have a growth rate that is 5-200% greater than the growth rate of MM294.

75. (Once Amended) A kit for cloning comprising a container containing [a rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

79. (Once Amended) The kit of claim 75, wherein said [rapid growing] *E. coli* contained within said kit are competent.

80. (Once Amended) The kit of claim 79, wherein said [rapid growing] *E. coli* contained within said kit are chemically competent.

81. (Once Amended) The kit of claim 79, wherein said [rapid growing] *E. coli* contained within said kit are electrocompetent.

82. (Once Amended) The kit of claim 75, wherein said [rapid growing] *E. coli* contained within said kit have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

83. (Once Amended) The kit of claim 75, wherein said [rapid growing] *E. coli* contained within said kit have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

84. (Once Amended) The kit of claim 75, wherein said [rapid growing] *E. coli* contained within said kit have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

85. (Once Amended) A composition comprising [rapid growing] *E. coli*, wherein said *E. coli* of said composition have a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B.

88. (Once Amended) The composition of claim 85, wherein said [rapid growing] *E. coli* of said composition have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

89. (Once Amended) The composition of claim 85, wherein said [rapid growing] *E. coli* of said composition have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

90. (Once Amended) The composition of claim 85, wherein said [rapid growing] *E. coli* of said composition have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

91. (Once Amended) A method of making competent [rapid growing] *E. coli*, comprising [the steps of]:

(a) obtaining [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B; and

(b) treating said [rapid growing] *E. coli* to make it competent.

92. (Once Amended) The method of claim 91, further comprising the step of curing said [rapid growing] *E. coli* of endogenous vectors.

93. (Once Amended) The method of claim 91, wherein said [rapid growing] *E. coli* are *E. coli* strain W or strain C.

94. (Once Amended) The method of claim 91, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294.

95. (Once Amended) The method of claim 91, wherein said [rapid growing] *E. coli* have a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α .

96. (Once Amended) The method of claim 91, wherein said [rapid growing] *E. coli* have a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294.

97. (Once Amended) Competent [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B; wherein said competent *E. coli* are produced according to the method of claim 91.

98. (Once Amended) Competent [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B; wherein said competent *E. coli* are produced according to the method of claim 92.

99. (Once Amended) Competent [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of a reference microorganism selected from the group consisting of *E. coli* MM294, DH5 α and DH10B; wherein said competent *E. coli* are produced according to the method of claim 93.

100. (Once Amended) Competent [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294; wherein said competent *E. coli* are produced according to the method of claim 94.

101. (Once Amended) Competent [rapid growing] *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* DH5 α ; wherein said competent *E. coli* are produced according to the method of claim 95.

102. (Once Amended) Competent [rapid growing] *E. coli* having a growth rate that is 5-200% greater than the growth rate of *E. coli* MM294; wherein said competent *E. coli* are produced according to the method of claim 96.

Please add new claims 103-129.